

# Compulsory Licensing or Disclosure Requirement? A Policy Instrument for Tackling Biopiracy in Southeast Asia

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*Biopiracy, largely defined as misappropriation and intellectual property control of biological resources and associated traditional knowledge, has long had profound adverse impacts on the lives of the people and communities in developing countries, including Southeast Asia, one of the global biodiversity hotspots. Given that patents are the main means used in most biopiracy cases to exploit resources and knowledge, this article will discuss its feasibility as the other policy instrument to tackle biopiracy in Southeast Asia and suggest how it should be established and/or improved. For this purpose, this article examines two policy instruments in the patent regime that can be and have been used to address the aforementioned problem: compulsory licensing and the disclosure requirement. Based on the analysis of these two instruments, this article discusses why compulsory licensing is an unlikely means of tackling the problem and suggests how a disclosure requirement can be established or improved to tackle biopiracy in the region.*

## Keywords

Biopiracy, Compulsory Licensing, Disclosure Requirement, Southeast Asia

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## I. Introduction

The biotechnology has offered diverse benefits in various aspects of our lives, such as life-saving drugs and more disease-or pest-resistant plant varieties. Nevertheless, such benefits have not been shared in an equal and fair manner, as shown by the misappropriation of biological resources and associated traditional knowledge, or biopiracy.<sup>1</sup>

Biopiracy has long existed all over the world, providing vast amounts of profit to companies in developed countries, but leaving behind developing countries, most of which provide the resources for them. Southeast Asia, one of the global biodiversity hotspots, has also been plagued by the exploitation of its biological resources and associated traditional knowledge, as shown in some biopiracy cases. Many companies, including multinational corporations (MNCs) involved in biopiracy cases, obtain intellectual property rights, especially patents, to protect their exclusive rights to their ‘inventions,’ as found in the definitions and cases of biopiracy. Such exclusive protection of their rights hinders developing countries, including Southeast Asian countries, from accessing the benefits resulting from the patents.

Accordingly, given that patents are the main means used in many biopiracy cases (in Southeast Asia), the primary purpose of this research is to focus on two policy instruments in the patent regime that could be or have been used to tackle biopiracy in Southeast Asia, examining whether they can contribute to addressing the problem in the region and, if so, how they must be established or improved.

The first policy instrument is “compulsory licensing” which has drawn relatively less attention as a means of tackling biopiracy. Largely defined as allowing someone else to produce a patented product or process without the consent of the patent owner,<sup>2</sup> compulsory licensing has mainly been regarded as an instrument to ensure access to pharmaceuticals.<sup>3</sup> Although this measure has rarely (or, never) been discussed as an instrument to tackle biopiracy, this article will discuss the feasibility

<sup>1</sup> DANIEL ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES 14-22 (2010). *See also* IKECHI MGBEOJI, GLOBAL BIOPIRACY: PATENTS, PLANTS AND INDIGENOUS KNOWLEDGE 9-49 (2006); Vandana Shiva, *Bioprospecting as Sophisticated Biopiracy*, 32(2) SIGNS 307 (2007).

<sup>2</sup> WTO, Compulsory Licensing of Pharmaceuticals and TRIPS, [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faqs\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faqs_e.htm).

<sup>3</sup> William Reinsch et al., *Compulsory Licensing: A Cure for Distributing the Cure* (CSIS, May 8, 2020), <https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure>. *See also* Eduardo Urias & Shyama Ramani, *Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence*, 3(4) J. INT’L BUS. POL’Y 384 (2020).

of using it to address the problem because most of the MNCs mainly used the patents to commit biopiracy, while compulsory licensing can be taken ‘against’ the exclusive protection under patents obtained in biopiracy.

The other policy instrument is the “disclosure requirement, i.e., a requirement to disclose the source and country of origin of the biological resource and traditional knowledge used in an invention of patent in question. In fact, unlike compulsory licensing, the disclosure requirement has long been debated as a means of tackling biopiracy and already been used to tackle biopiracy in some countries, although the forms adopted differ as discussed below in this article. To tackle biopiracy, the patent applicants are required to prove the origin of the resources and knowledge used in their inventions and whether these resources and knowledge are obtained with the consent of those who conserve them. Accordingly, this article will discuss its feasibility as the other policy instrument to tackle biopiracy in Southeast Asia and suggest how it should be established and/or improved.

For this purpose, Part two will survey some cases in Southeast Asia in connection with biopiracy. Part three will analyze compulsory licensing, focusing on its grounds and conditions in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). As there are challenges to the use of compulsory licensing as a means of tackling biopiracy, this article will suggest how the disclosure requirement must be established or improved to tackle biopiracy in Southeast Asia.

## II. Definition of Biopiracy and Biopiracy Cases in Southeast Asia

### A. Definition

Biopiracy may be defined as “intellectual property control including patents, or misappropriation of biological resources and/or associated traditional knowledge from other (usually developing) countries, indigenous peoples and local communities without adequate authorization and benefit sharing.”<sup>4</sup> Although biopiracy has been found to take different forms,<sup>5</sup> this article analyzes two biopiracy cases found in

<sup>4</sup> ROBINSON, *supra* note 1, at 20-1.

<sup>5</sup> *Id.* at 45-100. For instance, the author discusses a number of biopiracy cases, including those involving intellectual property control of the resources and knowledge.

Southeast Asia.

## B. Biopiracy Cases

### 1. Plao Noi case

Plao Noi, a local herb in Thailand, has long been known for its healing properties, recorded in traditional palm leaf books for centuries.<sup>6</sup> As traditional healers in Thailand have used its leaves and stem barks to treat ulcers with anti-ulcer effects for hundreds of years, some products containing the herb are being sold as tea bags and in powder form in herbal markets.<sup>7</sup>

Sankyo Company Ltd., one of the biggest pharmaceutical companies in Japan, filed applications for and was granted patents on the process and compounds of Plao Noi, including plaunotol, in some countries, including Japan, the US and Thailand. In particular, the compound plaunotol is marketed in tablet form under the brand name Kelnac, with annual sales in Thailand alone of USD 20 million.<sup>8</sup> However, Sankyo Co. did not share its benefits with the Thai government or local communities, except one Thai botanist who joined the collection of the samples, despite that the herb is widely grown in Thailand and many local communities have made enormous contributions to its conservation.<sup>9</sup>

### 2. Kwao Krua case

Kwao Krua, a group of leguminous plants, has long been used as a traditional herbal medicine not only in Thailand, but also in traditional indigenous communities in other parts of Southeast Asia.<sup>10</sup> As the herb has been known to have various medicine properties, such as breast enlargement and skin rejuvenation, it is used as a dietary supplement in Thailand.<sup>11</sup> When Kwao Krua's properties became famous, numerous patents were filed on inventions that use its extracts.<sup>12</sup> The patent was granted to Thai and a South Korean company in the US on the plant's extract and methods for

<sup>6</sup> Assisi Foundation et al., *Biopiracy, TRIPS and the Patenting of Asia's Rice Bowl*, GRAIN (May 25, 1998), <https://www.grain.org/article/entries/27-biopiracy-trips-and-the-patenting-of-asia-s-rice-bowl>.

<sup>7</sup> Maslin Osathanunkul et al., *Refining DNA Barcoding Coupled High Resolution Melting for Discrimination of 12 Closely Related Croton Species*, 10(9) PLOS ONE 2 (2015).

<sup>8</sup> JOHN GILLESPIE & RANDALL PEERENBOOM, *REGULATION IN ASIA: PUSHING BACK ON GLOBALIZATION* 200 (2009).

<sup>9</sup> ROBINSON, *supra* note 1, at 65.

<sup>10</sup> Suchinda Malaiwittanon et al., *Androgenic Activity of the Thai Traditional Male Potency Herb, Butea superba Roxb., in Female Rats*, 121(1) J. ETHNOPHARMACOLOGY 123 (2009).

<sup>11</sup> Tharita Kitisripanya et al., *Development of an Enzyme-Linked Immunosorbent Assay for the Detection of Isomiroestrol, an Identical Marker, in White Kwao Krua Using a Monoclonal Antibody*, 137 J. PHARMA. & BIOMED. ANAL. 229 (2017).

<sup>12</sup> ROBINSON, *supra* note 1, at 65.

extracting and manufacturing it.<sup>13</sup>

In particular, the second patent (granted to a South Korean company in the US) made the Thai communities concerned because the steps taken for extraction in the patent are not different from the methods that traditional practitioners use.<sup>14</sup> Moreover, indigenous communities in Thailand complained that the patent had disturbed their customs related to the plant's ordinary production and use.<sup>15</sup> Furthermore, the plant was overexploited by poachers, which raised concerns about the conservation and sustainable use of the plant and forced the Thai government to list it as a restricted herb.<sup>16</sup> There is little doubt that such measures prevented communities from accessing and using the plant.

### C. Implications of the Cases

The above biopiracy cases demonstrate that some common characteristics of biopiracy provided in the definition above are also found in cases in Southeast Asia. First, intellectual property rights, particularly patents were granted on the 'inventions' based on some resources and knowledge in Southeast Asia. Second, institutions from developed countries obtained the patents on resources and knowledge found in developing countries. Third, no benefit sharing occurred with the people, particularly indigenous peoples and local communities who conserved them. Since the focus of this article is to discuss policy instruments to tackle biopiracy in the patent regime, analysis of the instruments will be followed.

## III. Compulsory Licensing in the IP regime and Its Feasibility for Tackling Biopiracy in Southeast Asia

### A. Compulsory Licensing in the TRIPS Agreement

The TRIPS Agreement is the most comprehensive international intellectual property (IP) agreement in existence and its Article 31 stipulates some conditions to be satisfied when a member state exercises compulsory license. Following the

<sup>13</sup> *Id.* at 57.

<sup>14</sup> Ryan Levy & Spencer Green, *Pharmaceuticals and Biopiracy: How the America Invents Act May Reduce the Misappropriation of Traditional Medicine*, 23(3) U. MIA. BUS. L. REV. 407 (2015).

<sup>15</sup> *Id.*

<sup>16</sup> ROBINSON, *supra* note 1, at 65.

most fundamental principle that authorization of a compulsory license should be considered on its individual merits,<sup>17</sup> Article 31 lays down some conditions or grounds for compulsory licensing. Although efforts to obtain authorization from the right holder on reasonable commercial terms and conditions should be made by the proposed user, some exceptions are also recognized, such as national emergencies, other circumstances of extreme urgency and cases of public non-commercial use.<sup>18</sup> In those cases, the aforementioned requirement may be waived, but some duties of a procedural nature must be fulfilled, including notifying the right holder of the compulsory licensing.<sup>19</sup> Moreover, the scope and duration of the use in such cases shall be limited to the purpose for any such use being authorized predominantly for the supply of the domestic market of the Member authorizing such use.<sup>20</sup>

Compulsory licensing shall be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur.<sup>21</sup> Finally, Article 31 stipulates the obligation to pay adequate remuneration in each case, and the legal validity of any decision relating to the authorization of the use and the remuneration provided is subject to judicial or other independent review.<sup>22</sup>

Based on Article 31 of the TRIPS Agreement, several decisions regarding compulsory licensing have been adopted. First, the Doha Declaration on the TRIPS Agreement and Public Health adopted in 2001 provides for the right of the WTO Member States to grant compulsory licensing. The Doha Declaration prescribes their freedom to determine the grounds upon which compulsory licensing shall be granted and their right to determine what constitutes a national emergency or other circumstances of extreme urgency, although these are recognized mainly in the context of protecting public health.<sup>23</sup> Another decision adopted in 2003, namely Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health allows the WTO Member States to grant compulsory licensing to export a pharmaceutical product to 'eligible' Member States facing a national emergency but lacking the manufacturing capacity necessary to produce the product. However, this is subject to some conditions, one of which is that only the amount necessary to meet the needs of the eligible importing Member State(s) may be manufactured under the

<sup>17</sup> TRIPS art. 31(a).

<sup>18</sup> *Id.* art. 31(b).

<sup>19</sup> *Id.*

<sup>20</sup> *Id.* art. 31(c) & (f).

<sup>21</sup> *Id.* art. 31(g).

<sup>22</sup> *Id.* art. 31(h), (i) & (f).

<sup>23</sup> WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/W/2, 41 I.L.M., ¶ 5 (2001).

license, and all the manufactured products shall be exported to the Member State(s).<sup>24</sup>

## B. State Practices

Although Article 31 of the TRIPS Agreement allows the WTO Member States to authorize compulsory licensing under certain conditions, not many cases have been found that Member States used compulsory licensing.<sup>25</sup> Even when used, it has taken various forms. Some governments merely ‘threaten’ to use compulsory licensing to achieve their goals, such as lower prices. For instance, after being pressured and threatened by some countries, including Roche, a US pharmaceutical company that owned a patent for Tamiflu, entered into negotiations to license the production of the life-saving drug in an effort to contain the global bird flu epidemic.<sup>26</sup>

However, other governments have occasionally authorized compulsory licensing for certain purposes. For instance, a bill adopted by the Brazilian government in 2005 suspended the patents owned by Abbott Laboratories, authorizing the local production of generic versions of all drugs for treating acquired immunodeficiency syndrome (AIDS).<sup>27</sup> The Brazilian government argued that the use of compulsory licensing in the aforementioned case was in line with the TRIPS Agreement because the patent was suspended temporarily due to a health emergency.<sup>28</sup> Another case in point is the Thai government’s authorization of a copy of the holder’s patent and domestic production of the AIDS drug Kaletra after failing to come to an agreement on price reduction.<sup>29</sup> The Thai government’s right to issue compulsory licensing under the TRIPS Agreement was acknowledged by the US.<sup>30</sup> Finally, Canada produced and exported an AIDS drug to Rwanda, a country incapable of manufacturing licensed products, by authorizing compulsory licensing based on the 2003 WTO decision in

<sup>24</sup> WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540, 43 I.L.M., ¶ 2(b)(i) (2003).

<sup>25</sup> Susy Frankel & Jessica Lai, *Recognized and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law’s Social Contract*, in *COMPULSORY LICENSING PRACTICAL EXPERIENCES AND WAYS FORWARD* 157 (Reto Hilty & Kung-Chung Liu eds., 2015). See also Jessica Fayerman, *The Spirit of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement*, 25(1) *Nw. J. INT’L L. & BUS.* 265 (2004); Lindor Qunaj et al., *Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis*, 100(1) *MILBANK Q.* (2022).

<sup>26</sup> Robert Fair, *Does Climate Change Justify Compulsory Licensing of Green Technology?*, 6(1) *BRIGHAM YOUNG U. INT’L L. & MGMT. REV.* 28 (2009).

<sup>27</sup> *Abbott Labs and Brazil Shake Hands on Discounted Kaletra*, *PHARMA TIMES* (July 5, 2007), [https://www.pharmatimes.com/news/abbott\\_labs\\_and\\_brazil\\_shake\\_hands\\_on\\_discounted\\_kaletra\\_990332](https://www.pharmatimes.com/news/abbott_labs_and_brazil_shake_hands_on_discounted_kaletra_990332).

<sup>28</sup> Fair, *supra* note 26, at 28.

<sup>29</sup> Charles Collins-Chase, *The Case against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29(3) *U. PA. J. INT’L L.* 788 (2008).

<sup>30</sup> Fair, *supra* note 26, at 28.

2007.<sup>31</sup> Although compulsory licensing has not been frequently issued by countries, the aforementioned cases show that some countries tend to authorize compulsory licensing for public purposes, including public health.

### **C. Can Compulsory Licensing Be Used by Southeast Asian states against Biopiracy?**

As noted above, biopiracy has given rise to many problems in diverse dimensions. For instance, in the *Plao Noi* case, few or even no benefits arising from the sales of plaunotol were shared with the Thai local communities. This shows that biopiracy deprives the people in Southeast Asian countries of the economic benefits that they deserve to obtain for their contribution to the conservation of the resources and associated traditional knowledge in question. Moreover, in the *Kwao Krua* case, the patents concerned were found to disturb the custom or culture of some indigenous communities in Thailand related to the plant's ordinary production and use. The patents also led to overexploitation of the plant (an environmental problem), which forced the government to list it as a restricted herb. No doubt such restrictive measures adversely affected the lives of the communities concerned.

To address the aforementioned problems, Southeast Asian countries may be tempted to grant compulsory licensing, so that local companies or public institutions can access patents and produce products (e.g. plaunotol) and indigenous peoples and local communities can be economically benefited. As noted earlier, Article 31 of the TRIPS Agreement does not regulate the right of the contracting parties to grant compulsory licensing. More specifically, while Article 31 requires efforts to obtain authorization from the right holder on reasonable commercial terms and conditions to be made, it also permits some 'exceptions' that allow for the granting of compulsory licensing without such efforts: national emergencies, circumstances of extreme emergency, and cases of public non-commercial use. Accordingly, it is argued that because the countries in the region do not have to make efforts to obtain authorization from patent holders, they will be likely to rely upon the above exceptions.

Furthermore, some decisions adopted by the contracting parties are in favor of their right or freedom to grant compulsory licensing. For instance, the Doha Declaration provides for countries' freedom to determine the grounds upon which compulsory licensing shall be granted and their right to determine what constitutes a national emergency or other circumstances of extreme emergency, albeit in the

<sup>31</sup> *Id.* at 29.



context of public health.<sup>32</sup>

Thus, based on the TRIPS Agreement and Doha Declaration, the governments facing the aforementioned problems of biopiracy are likely to grant compulsory licensing on the ground that the impacts of biopiracy constitute a “national emergency” or “circumstances of extreme urgency,” although “cases of public non-commercial use” probably cannot be invoked because the technology in a given patent can be accessed by commercial enterprises in such cases. In fact, as Article 31 of the TRIPS Agreement neither provides definite parameters for determining the scope of the grounds, nor regulate the right of the Member States to stipulate the grounds for resorting to compulsory licensing, more discretion is given to the governments of Southeast Asian countries willing to grant compulsory licensing.<sup>33</sup> Moreover, although some countries are reluctant to compulsory licensing, others in the above cases issued compulsory licensing which show their tendency to use the policy instrument to tackle problems<sup>34</sup> including biopiracy.

Overall, the negative economic, cultural and environmental impacts of biopiracy can urge the governments facing them in the region to take action to tackle biopiracy. As compulsory licensing enables the people affected to have access to the products in question in a more affordable manner, these governments are likely to consider the measure. However, there are some factors that governments in the concerned region should take into account when exercising compulsory licensing that may prevent them from implementing the measure. First, although the aforementioned adverse impacts of biopiracy can be regarded as a concern for the countries in the region, they will probably not be considered “national emergencies or other circumstances of extreme urgency,” as provided in Article 31. This is because apart from the fact that the impacts may not be as grave as a problem such as pandemic, in most cases, biopiracy has a direct impact only on some people in a country, particularly indigenous peoples and local communities.

In other words, biopiracy affects people differently. It means that some people will not consider it as a national emergency or a circumstance of extreme urgency. In fact, when it comes to determining national emergencies or other circumstances of extreme urgency, compulsory licensing should not be granted on frivolous grounds.<sup>35</sup>

<sup>32</sup> Kuei-Jung Ni, *Legal Aspects (Barriers) of Granting Compulsory Licenses for Clean Technologies in Light of WTO/TRIPS Rules: Promise or Mirage*, 14 WORLD TRADE REV. 714 (2015).

<sup>33</sup> *Id.* at 713.

<sup>34</sup> Hilary Wong, *The Case for Compulsory Licensing during COVID-19*, 10(1) VIEWPOINTS 2 (2020). See also Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18(2) J. INTELL. PROP. L. 386-94 (2011).

<sup>35</sup> NUNO CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 436 (2010).

It should not be granted for individual benefits at the expense of eroding the rights of the patent holder, and only “exceptional and critical situations” should be allowed.<sup>36</sup> Such a restrictive approach was supported by many developed countries during the Uruguay Round negotiations.<sup>37</sup>

Moreover, the risk of the patent holder and its home authorities taking legal action cannot be ignored. For instance, the decision of the Taiwanese Intellectual Property Office to grant compulsory licensing of the Philips CD-R patents to the local company triggered a fierce protest from the EC which argued that the measure is a violation of the TRIPS Agreement.<sup>38</sup> Such a backlash by the patent holder and its home authorities against compulsory licensing could lead to a legal action either in a domestic court or the WTO dispute settlement mechanism, which if it occurs, will cost a Southeast Asian country a fortune. Furthermore, developed countries can impose sanctions on a Southeast Asian country in response to compulsory licensing. For instance, when Thailand granted compulsory licensing for the AIDS drug Kaletra, the US included it in the Priority Watch List, which increased the possibility of the imposition of trade sanctions.<sup>39</sup>

Therefore, although Southeast Asian countries can be tempted to consider compulsory licensing to tackle biopiracy, given the aforementioned challenges and the high likelihood of experiencing backlashes from developed countries, it will be extremely difficult for them to use compulsory licensing as a means of tackling biopiracy.

## IV. The Disclosure Requirement as an Alternative to Tackle Biopiracy in Southeast Asia

Based on the discussion in the previous section where compulsory licensing is not a likely option to tackle biopiracy for Southeast Asian countries, Part four will focus on the “disclosure requirement” which is another mechanism in the patent regime as a means of tackling biopiracy. The disclosure requirement means a requirement

<sup>36</sup> *Id.*

<sup>37</sup> Draft Agreement on TRIPS: Communication from the United States, WIPO Doc. MTN.GNG/NG11/W/70, 11 (1990), <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W70.PDF>.

<sup>38</sup> Ni, *supra* note 32, at 715.

<sup>39</sup> David Miller, *Combating Copyright Infringement in Russia: A Comprehensive Approach for Western Plaintiffs*, 33(5) VAND. J. TRANSNAT'L L. 1214 (2000).

to make it mandatory to disclose in patent applications the source and/or country of origin of biological resources, or associated traditional knowledge and legal acquisition of such resources, if such resources and/or traditional knowledge are contained in an invention over which an applicant is seeking patent rights.<sup>40</sup> It has long been discussed as a means of tackling biopiracy in some international patent regimes by obliging patent applicants to disclose the origins of the biological resources and associated traditional knowledge used in their inventions. In this course, the disclosure requirement can ensure that these were obtained with the consent of the people who conserve and develop them, including indigenous people and local communities.

However, the disclosure requirement has generated clashes between developed and developing countries primarily because while the former is hostile to the requirement, the latter is favorable. Accordingly, the author will first discuss how different their positions have been in the international regimes in relation to the requirement. On that basis, he will suggest how the requirement can be established or improved in Southeast Asia, so that it can play a role as an alternative to compulsory licensing to tackle biopiracy in Southeast Asia.

## A. The Disclosure Requirement in International Patent Regimes

The disclosure requirement has been discussed in two international patent regimes such as: the WTO TRIPS Council and the World Intellectual Property Organization (WIPO)'s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The Member States of both regimes have maintained similar stances in relation to the disclosure requirement.<sup>41</sup>

First, developed countries, such as the US and Japan, are largely skeptical of the disclosure requirement in tackling biopiracy. For instance, it has been argued that the requirement will place too much burden on patent applicants, which

<sup>40</sup> UNCTAD, THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE NAGOYA PROTOCOL: INTELLECTUAL PROPERTY IMPLICATIONS 47 (2014), [https://unctad.org/system/files/official-document/diaepcb2014d3\\_en.pdf](https://unctad.org/system/files/official-document/diaepcb2014d3_en.pdf).

<sup>41</sup> Regarding the disclosure requirement, as of this writing, text-based negotiations to finalize an agreement on an international legal instrument relating to intellectual property are still going. Accordingly, this article focuses on the stances maintained by the Member States on the requirement during the past debates. See WTO, Background and the Current Situation, [https://www.wto.org/english/tratop\\_e/trip\\_e/art27\\_3b\\_background\\_e.htm](https://www.wto.org/english/tratop_e/trip_e/art27_3b_background_e.htm); WIPO Secretariat, Update of the Technical Review of Key Intellectual Property Related Issues of the WIPO Draft Instruments on Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions within the Framework of Indigenous Human Rights, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO Doc. WIPO/GRTKF/IC/45/INF/8, ¶ 27 (2022), [https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_45/wipo\\_grtkf\\_ic\\_45\\_inf\\_8.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_45/wipo_grtkf_ic_45_inf_8.pdf).

will discourage research and development (R&D).<sup>42</sup> Moreover, some developed countries are concerned that the disclosure requirement violates Article 27(1) of the TRIPS Agreement, which provides that as long as an invention is new, involves an inventive step, and is capable of industrial application, a patent should be granted.<sup>43</sup> Particularly, the US asserted that tailored and national solutions to prevent bad patents would be more desirable as it was doubtful of the effectiveness of “merely conveying the information indicating the country of origin, ex situ collection sites, etc.” in preventing biopiracy.<sup>44</sup> Furthermore, Japan pointed out that risks and difficulties in identifying the source or origin and traceability of the resources and associated traditional knowledge on which an invention is based could discourage motivation and make industries hide their inventions as trade secrets rather than filing patent applications.<sup>45</sup>

Meanwhile, developing countries have maintained that the patent system can be more transparent and bad patents that freeride on the assets of people and communities in developing countries can be prevented by introducing a disclosure requirement. Particularly given that such entities as MNCs usually exploit the resources and knowledge in most cases, it is important for developed countries to implement the disclosure requirement.<sup>46</sup> In addition, at a WTO meeting, India argued that the Member States should require an applicant for a patent relating to a biological material or traditional knowledge to disclose the origin of the resource and knowledge used and to provide evidence of both prior informed consent, and fair and equitable sharing of the benefits obtained, as a condition to acquiring patent rights.<sup>47</sup> Particularly, Brazil stated that the disclosure requirement is the most effective solution to misappropriation, adding that the requirement should cover patents involving access to genetic resources, their derivatives and associated traditional knowledge, in accordance with the Convention on Biological Diversity and national legislation.<sup>48</sup>

Finally, some European countries, unlike the US or Japan, have largely been

<sup>42</sup> Laura Grebe, *Requiring Genetic Source Disclosure in the US*, 44 CREIGHTON L. REV. 395 (2011).

<sup>43</sup> *Id.*

<sup>44</sup> Paul Kuruk, *Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy*, 17 SAN DIEGO INT'L L. J. 45 (2015).

<sup>45</sup> WIPO Secretariat, Draft Report, WIPO Doc. WIPO/GRTKF/IC/23/8 PROV. 60 (Apr. 26, 2013).

<sup>46</sup> Emanuela Arezzo, *Struggling around the “Natural Divide”: The Protection of Tangible and Intangible Indigenous Property*, 25(1) CARDOZO ARTS & ENT. L. J. 380 (2008).

<sup>47</sup> The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, WTO Doc. IP/C/W/356 (June 24, 2002).

<sup>48</sup> WIPO Secretariat, *supra* note 45, at 63.

supportive of introducing the disclosure requirement into the international intellectual property regimes. However, they are also on the same page as other developed countries in some respects. While the European Community (EC) countries agreed to introduce the disclosure requirement, they made it clear that: “Such a disclosure requirement should not act, de facto or de jure, as an additional formal or substantial patentability criterion. ...”<sup>49</sup> and “Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law.”<sup>50</sup> Particularly, Switzerland at some meetings of the WIPO intergovernmental committees explicitly indicated that the disclosure should be optional, not mandatory, partly because the least developed countries lack the capacity to implement the requirement at the national level.<sup>51</sup> In addition, Switzerland refused to revoke or invalidate patents that had been granted despite the applicants’ failure to comply with the disclosure requirement, suggesting other sanctions, such as criminal sanctions.<sup>52</sup> Likewise, the EC argued that the submission of incorrect or incomplete information should not invalidate the granted patent and it must be left to the individual states to determine the character, but level of the sanctions, although it supported requiring disclosure.<sup>53</sup>

In summary, while developing countries have largely supported the disclosure requirement to prevent biopiracy, developed countries like the US and Japan have been generally opposed to it for its adverse impact on the patent system. Meanwhile, the EC Member States have supported the requirement, but they have been against invalidating a patent already granted when the patent applicant fails to meet the requirement.

## B. Disclosure Requirement in the Patent Instruments in Southeast Asia

Despite the controversy over the effectiveness of the disclosure requirement to tackle biopiracy, the author would argue that the requirement should be incorporated into the intellectual property regime in Southeast Asia as a means to tackle biopiracy

<sup>49</sup> Review of Article 27.3(B) of the Trips Agreement, and the Relationship between the Trips Agreement and The Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore, WTO Doc. IP/C/W/383, (Oct. 17, 2002).

<sup>50</sup> *Id.*

<sup>51</sup> Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland, WIPO Doc. WIPO/GRTKF/IWG/3/4, ¶¶ 22-3 (Jan. 10, 2011).

<sup>52</sup> *Id.* at ¶ 27.

<sup>53</sup> Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications: Document Submitted by the European Community and Its Member States, WIPO Doc. WIPO/GRTKF/IC/8/11, 2 & 6 (Dec. 15, 2010).

for some reasons. First, the requirement can make a patent system more legitimate because the bad patents that freeride on the assets of people and communities in developing countries can be tackled. Moreover, given that bad patents led to overexploitation of the resource in question, the requirement can contribute to more sustainable ‘bioprospecting,’ not ‘biopiracy.’

However, as countries have shown some differences in their preferred forms of disclosure requirement, this section will discuss how a disclosure requirement could be established or improved in Southeast Asia to tackle biopiracy in the region. To that end, this section will first discuss the current intellectual property regimes at the regional and domestic levels, suggesting how to improve them to tackle biopiracy.

### 1. Regional Level: Current Status and How to Improve the IP Regime

The Association of Southeast Asian Nations (ASEAN) has adopted a number of regional policy instruments which address intellectual property rights among the Member States. Among those instruments, the author focuses on the ASEAN Framework Agreement on Intellectual Property Cooperation because it is the only binding intellectual property instrument in the region. The Agreement aims to strengthen the cooperation in the field of intellectual property among the ASEAN government agencies and private sectors. It requires the Member States to have consultations with each other on the development of their intellectual property regimes, with a view to creating ASEAN standards and practices.<sup>54</sup> Moreover, some cooperation activities are listed to enhance the cooperation in intellectual property enforcement and protection among the Member States, such as “networking of judicial authorities and intellectual property enforcement agencies” and “creation of an ASEAN database on intellectual property registration.”<sup>55</sup> Although the Agreement has laid the groundwork for the cooperation on the protection and enforcement of intellectual property rights in the region, however, it is merely a set of broad principles without specific mechanism for implementation. In particular, no provisions are tackling biopiracy, such as a disclosure requirement in the ASEAN Framework Agreement.

In addition to the aforementioned Agreement, ASEAN established the ASEAN Working Group on Intellectual Property Cooperation (AWGIPC) in 1996 to address matters concerning intellectual property rights in the region.<sup>56</sup> As an organization established to carry out the necessary actions for the Agreement, the AWGIPC has

<sup>54</sup> ASEAN Framework Agreement on Intellectual Property Cooperation, art. 1.

<sup>55</sup> *Id.* art. 3.

<sup>56</sup> ASEAN Intellectual Property Portal, About, <https://www.ascanip.org/about>.

played important roles. Composed of the heads of the national intellectual property offices of the ASEAN Member States, it serves as a consultative body for ASEAN on intellectual property issues and as the primary source of technical assistance, training and capacity-building cooperation with foreign donors and international agencies.<sup>57</sup> While the AWGIPC provides a variety of advice and services to ASEAN on matters pertaining to intellectual property rights, it has not established any mechanisms or institutions for monitoring compliance with the ASEAN Framework Agreement.

Although the ASEAN Framework Agreement lists some provisions of cooperative activities (8 general activities and 11 specific ones), none of them deal specifically with biopiracy. Thus, this article suggests that the ASEAN Framework Agreement provide cooperative activities designed to tackle biopiracy, which may be referred to as “Activities to make the ASEAN intellectual property system more environment-friendly.” Together with some specific activities to that end, it includes “the introduction of the requirement to disclose the origins of the biological resources and traditional knowledge used in inventions for patent protection into the patent laws of the contracting parties.” In so doing, the ASEAN Member States would be required to implement these two cooperative activities, which will lead the ASEAN intellectual property system to be more environment- or biodiversity-friendly preventing biopiracy. In particular, Article 6 of the ASEAN Framework Agreement<sup>58</sup> may significantly limit the effect of this Agreement because the ASEAN Member States can easily disregard the obligations in the Agreement under this provision, including the introduction of a disclosure requirement. Article 6 should be removed from the Agreement. Meanwhile, AWGIPC should facilitate the implementation of the ASEAN Framework Agreement by the ASEAN member states to tackle biopiracy in the region. As a consultative body for ASEAN on intellectual property issues, the Working Group should encourage the Member States to ratify the ASEAN Framework Agreement for more coherent protection and enforcement of intellectual property rights in the region. To this end, the AWGIPC should provide the ASEAN Member States with advice or assistance, such as sharing and exchanging information on intellectual property laws and institutions including the disclosure requirement. With these consultative activities, AWGIPC can not only help tackle biopiracy more effectively at the regional level, but also improve compliance with the ASEAN

<sup>57</sup> Peter Fowler et al., *ASEAN and Intellectual Property: Will a Complicated History Lead to a Certain Future?*, 40(2) *Loy. L.A. INT'L & COMP. L. REV.* 184 (2017).

<sup>58</sup> ASEAN Framework Agreement art. 6. It provides: “Nothing in this Agreement shall prejudice any existing or future bilateral or multilateral agreement entered into force by any Member State or the national laws of each Member State relating to the protection and enforcement of intellectual property rights.”

Framework Agreement.

## 2. National Level: Current Status and the Way to Improve the Laws and Institutions

Recognizing the importance of intellectual property for economic development, all the ASEAN Member States have set up intellectual property system to protect intellectual property rights.<sup>59</sup> However, most of them have not incorporated a disclosure requirement into their laws and particularly, even the countries with the disclosure requirement have problems in implementing the requirement.

According to a survey of the legal texts of patent laws by WIPO, only three (Indonesia, the Philippines and Vietnam) out of the ten ASEAN countries have a disclosure requirement in their respective patent laws.<sup>60</sup> However, the disclosure requirements in their laws are different particularly in terms of the consequences of non-compliance with the requirement.

First, Article 26 of the Law of the Republic of Indonesia No. 13 of July 28, 2016 on Patents makes it mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in the patent description if an invention is associated with a genetic resource and/or traditional knowledge.<sup>61</sup> It also stipulates that Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub-article (1) is conducted based on national and international laws in the realm of genetic resources and traditional knowledge.<sup>62</sup> In addition, Article 35 of the Law No. 13 stipulates that a written reminder should be sent to the applicant for him/her to meet the requirement and that the period for meeting the requirement can be extended upon the request of the applicant. However, if the applicant ultimately fails to meet the requirement in spite of the extension(s), no consequences are provided in the law.

Second, the Philippines Technology Transfer Act of 2009 requires all patent applications to disclose any biodiversity and genetic resources, traditional knowledge and indigenous knowledge, systems and practices used in the inventions.<sup>63</sup> In addition, the Implementing Rules and Regulations of Republic Act No. 10055 provides that the requirement must apply when the subject matter contained in a national or international intellectual property right application is directly based

<sup>59</sup> CHRISTOPH ANTONS & MICHAEL BLAKENEY, *INTELLECTUAL PROPERTY LAW IN SOUTHEAST Asia* 18-215 (2023).

<sup>60</sup> WIPO, Annex: Disclosure Requirements Table, [https://www.wipo.int/export/sites/www/tk/en/docs/genetic\\_resources\\_disclosure.pdf](https://www.wipo.int/export/sites/www/tk/en/docs/genetic_resources_disclosure.pdf)

<sup>61</sup> Law of the Republic of Indonesia No. 13 of July 28, 2016 on Patents, art. 26(1).

<sup>62</sup> *Id.* art. 26 (3).

<sup>63</sup> The Philippines Technology Transfer Act of 2009, art. III, §8(c).



on the above resources and knowledge.<sup>64</sup> However, the Implementing Rules and Regulations also stipulate that if R&D institutes do not have the necessary information to meet the disclosure requirement for reasons beyond their control, they are required to submit an affidavit and state the reason(s) for their inability to fulfill the requirement, which shall be subject to review by the government funding agencies to determine if it constitutes compliance with the disclosure requirement under this rule.<sup>65</sup> In particular, the Implementing Rules and Regulations provide that such disclosure may not be required for the grant or issuance of a certificate of intellectual property registration, which means that the requirement can sometimes be waived.<sup>66</sup>

Finally, under the Circular No. 01/2007/TT-BKHCHN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property, a patent application must include documents explaining the origin of the genetic resource and/or traditional knowledge accessed by the inventor or applicant.<sup>67</sup> If such origin cannot be identified, the applicant is required to bear responsibility for the truthfulness of their declaration.<sup>68</sup> Apart from bearing responsibility, no other consequences of non-compliance with the requirement are provided. In other words, even when the applicant is not able to find the origin of the genetic resource and/or traditional knowledge used in their invention, the only consequence is "bearing responsibility for the truthfulness of their declaration," which is too vague.

In Southeast Asia, only these three countries have a disclosure requirement in their respective patent laws. Moreover, lack of consequences of non-compliance with the disclosure requirement in all of the above laws weakens their effectiveness to tackle biopiracy because companies from developed countries can still obtain patents in the region based on their 'spurious' inventions, which can facilitate rather than prevent biopiracy. In particular, it can lead government to promote the interests of the companies, at the expense of the indigenous peoples and local communities. In this regard, the author would suggest the following key components of a model disclosure requirement to tackle biopiracy in the Southeast Asian region.

<sup>64</sup> Implementing Rules and Regulations of Republic Act No. 10055, rule 12, §3(c)(ii).

<sup>65</sup> *Id.* rule 12, §3(c)(iii).

<sup>66</sup> *Id.* rule 12, §3(c)(v).

<sup>67</sup> Circular No. 01/2007/TT-BKHCHN of Feb. 14, 2007, Guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of Sept. 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property, art. 23.11.

<sup>68</sup> *Id.*

First, all other ASEAN Member States which do not have the requirement yet should make it mandatory to disclose the origin of the genetic resource and associated traditional knowledge used in an invention subject to a patent application if the invention in question is based on genetic resources and/or traditional knowledge, like Indonesia, the Philippines and Vietnam. However, the requirement should be supplemented by some instruments to ensure that the origin stated is not false and the concerned resource and/or knowledge is not exploited. Accordingly, prior informed consent and/or benefit-sharing agreements concluded with peoples and governments in countries where the resources and knowledge at stake are obtained and have been conserved (usually developing countries) should be required because they can show that the resources and knowledge are not exploited but are obtained with the consent of the peoples and government in their countries of origin. Furthermore, given that the above laws do not have any consequences of non-compliance with the requirement, a mechanism or instrument that puts such consequences in place needs to be introduced.

As discussed earlier, most developing countries are in favor of introducing a disclosure requirement in their respective patent laws, some of which have consequences. For instance, the Patent Amendment Act 2005 in South Africa establishes a disclosure requirement, requiring every applicant who lodges an application for a patent to state “whether or not the invention is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use, and, if so, furnish proof as to his or her title or authority to make use of the resource or traditional knowledge.”<sup>69</sup> Particularly, if such a statement or declaration turns out to be false, the Act 2005 states that it may be a ground for the revocation of the patent.<sup>70</sup> The possibility to revoke a patent in question for failing to observe the requirement and obtain resources and knowledge with prior informed consent (and benefit sharing agreement) serves as a means to ensure compliance by patent applicants.

Conversely, most developed countries have been opposed to introducing a disclosure requirement into their intellectual property regimes. However, some European countries are on the same page as developing countries in relation to the use of the requirement as a means of tackling biopiracy, although they show some differences, especially in terms of the consequences of failure to meet the requirement.

<sup>69</sup> Patent Amendment Act 2005 (South Africa), § 25(3)(a) & (b).

<sup>70</sup> Adejoke Oyewunmi, *Sharpening the Legal Tools to Overcome Biopiracy in Africa through Pro-Development Implementation of Normative International Standards: Lessons from Brazil, South Africa, and India*, 21(3) AFR. J. INT’L & COMP. L. 462 (2013).

For instance, the National Patent Act in Switzerland distinguishes between “pre-grant” and “post-grant” sanctions. In the former, if the disclosure requirement is not met, a timeline is set for the applicant to remedy the deficiencies, and the application will be rejected if the deficiencies are not remedied within the timeline.<sup>71</sup> In the latter, if the applicant intentionally provided false information, they would be subjected to a fine of up to 100,000 Swiss francs, and the judgment could be published, although the patent would not be revoked.<sup>72</sup> As a result, the law introduces sanctions outside the patent regime instead of revoking the patents granted.

As noted earlier, the three ASEAN Member States that have a disclosure requirement in their respective patent laws have not stipulated any consequence for failure to meet the requirement. Accordingly, some consequences should be put in place. The foregoing discussions largely show two kinds of consequences of non-compliance with the disclosure requirement: (1) revocation of patents and (2) sanctions not affecting the patents. Although the revocation of patents can play an active role in preventing biopiracy, on the one hand, it will risk making the patent system unstable. On the other, the lack of consequence can play no role or only a minimal role in enforcing the disclosure requirement because the patent applicants will not be affected by their failure to meet the requirement. Such a lack of legal remedy thus can ‘facilitate’ biopiracy and lead government to be caught by the interests of MNCs, at the expense of the indigenous peoples and local communities.

The author would suggest that the sanctions not affecting patents approach, namely imposing fines or other penalties such as sharing a certain share of royalties arising from the patents obtained through biopiracy without affecting the patent applications or patents granted be the most desirable solution because it has some consequences for non-compliance with the disclosure requirement, but does little to make the patent system unstable through the invalidation of the patents already granted. Therefore, this approach should be incorporated into the national patent regimes in Southeast Asia.

<sup>71</sup> Swiss Patents Act arts. 59(2) & 59 a (3), ¶ b.

<sup>72</sup> *Id.* art. 81(a). See also Georges Bauer et al., *Disclosure Requirements*, in *PROTECTING TRADITIONAL KNOWLEDGE: THE WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE 250* (Daniel Robinson et al. eds., 2017).

## V. Conclusion

Biopiracy has long plagued many parts of the developing world, bringing about the unfair use and exploitation of biological resources and associated traditional knowledge. Southeast Asia, one of the global biopiracy hotspots, has not been immune to this problem.

This article has discussed two intellectual property policy instruments that can tackle biopiracy in the region: compulsory licensing and the disclosure requirement. Although developing countries, including the ASEAN Member States, can be tempted to exercise compulsory licensing to tackle biopiracy by taking action against patents obtained without prior informed consent and benefit sharing, they are unlikely to do this for certain reasons, including the risk of legal action by the patent holder and its home country. Meanwhile, the requirement to disclose the origin of the biological resource and/or associated traditional knowledge used in an invention that is the subject of a patent application is specifically discussed as it can help tackle biopiracy in Southeast Asia. Particularly, considering that even three ASEAN Member States with a disclosure requirement in their domestic patent laws do not have a mechanism to ensure compliance, the author has suggested how the consequences of the non-compliance with the requirement should be stipulated in their laws based on how intellectual property instruments at the regional level should be improved.

Overall, if some improvements are made to enable the disclosure requirement to tackle biopiracy at the domestic and regional levels in Southeast Asia, the biological resources and associated traditional knowledge in the region can be used more sustainably. As a consequence, although compulsory licensing is an unlikely option for tackling biopiracy, it is argued that the slim chance of implementing it can contribute to some extent to ‘preventing’ biopiracy in Southeast Asia.

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